

there is no principal importer under paragraph (b)(2) of this section, liable for complying with this part, for completing the MCAN, and for the completeness and truthfulness of all information which it submits.

(c) *Manufacturers, importers, or processors of microorganisms for a significant new use.* MCAN submission is required for any person who intends to manufacture, import, or process for commercial purposes a microorganism identified as having one or more significant new uses in subpart M of this part, and who intends either to engage in a designated significant new use of the microorganism or intends to distribute it in commerce. Persons excluded from reporting on significant new uses of microorganisms and additional procedures for reporting are described in subpart L of this part.

§ 725.110 Persons not subject to this subpart.

Persons are not subject to the requirements of this subpart for the following activities:

(a) Manufacturing, importing, or processing solely for research and development microorganisms that meet the requirements for an exemption under subpart E of this part.

(b) Manufacturing, importing, or processing microorganisms for test marketing activities which have been granted an exemption under subpart F of this part.

(c) Manufacturing or importing new microorganisms under the conditions of a Tier I or Tier II exemption under subpart G of this part.

§ 725.150 Procedural requirements for this subpart.

General requirements for all MCANs under this part are contained in subparts A through C of this part. In addition, the following requirements apply to MCANs submitted under this subpart:

(a) *When to submit a MCAN.* A MCAN must be submitted at least 90 calendar days prior to manufacturing or importing a new microorganism and at least 90 calendar days prior to manufacturing, importing, or processing a microorganism for a significant new use.

(b) *Section 5(b) of the Act.* The submitter must comply with any applicable requirement of section 5(b) of the Act for the submission of test data.

(c) *Contents of a MCAN.* Each person who submits a MCAN under this subpart must provide the information and test data described in §§ 725.155 and 725.160.

(d) *Recordkeeping.* Each person who submits a MCAN under this subpart must comply with the recordkeeping requirements of § 725.65.

§ 725.155 Information to be included in the MCAN.

(a) Each person who is required by this part to submit a MCAN must include the information specified in paragraphs (c) through (h) of this section, to the extent it is known to or reasonably ascertainable by that person. However, no person is required to include information which relates solely to exposure of humans or ecological populations outside of the United States.

(b) Each person should also submit, in writing, all other information known to or reasonably ascertainable by that person that would permit EPA to make a reasoned evaluation of the health and environmental effects of the microorganism, or any microbial mixture or article, including information on its effects on humans, animals, plants, and other microorganisms, and in the environment. The information to be submitted under this subpart includes the information listed in paragraphs (c) through (h) of this section relating to the manufacture, processing, distribution in commerce, use, and disposal of the new microorganism.

(c) *Submitter identification.* (1) The name and headquarters address of the submitter.

(2) The name, address, and office telephone number (including area code) of the principal technical contact representing the submitter.

(d) *Microorganism identity information.* Persons must submit sufficient information to allow the microorganism to be accurately and unambiguously identified for listing purposes as required by § 725.12.

(1) *Description of the recipient microorganism and the new microorganism.* (i)